

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON TALCUM:
POWDER PRODUCTS MARKETING,:
SALES PRACTICES AND PRODUCTS:
LIABILITY LITIGATION : Civil Action No. 3:16-md-2738-FLW-LHG
: MDL No. 2738

: **ORDER REGARDING PATHOLOGY
EVIDENCE PRESERVATION
PROTOCOL**
:

I. SCOPE OF ORDER

1. Discovery in this proceeding may involve the collection, division, storage, preservation and production of pathology evidence for which, special handling, division, storage and preservation procedures may be warranted. This Order will apply to all current and future actions in MDL No. 2738, until further order of the Court.

II. THE ORDER

2. By stipulating to this Pathology Evidence Protocol Order, the parties have agreed to be bound by its terms and to request its entry by the presiding judge. It is hereby **ORDERED** as follows:

This stipulation is entered between Plaintiffs and Defendants (hereinafter each a "Party" or collectively, the "Parties"), by and through their respective counsel, to provide a protocol for the collection, preservation, storage, and division of the Materials in the Litigation (as defined in section III, below).

III. DEFINITIONS

3. "Facility"/"Facilities" is defined to include healthcare facilities that provided care and treatment to a Plaintiff and facilities responsible for the preservation and/or maintenance of excised tissue from a Plaintiff. .

4. "Litigation" is defined as IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS, LIABILITY, MDL No. 16-2738, pending in the United States District Court for the District of New Jersey, including all current and future member cases transferred, removed to, or filed in this district.

5. "Defendants" is defined as Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer"), Imerys Talc America, Inc. f/k/a Luzenac America, Inc. ("Imerys Talc") and Personal Care Products Council ("PCPC").

6. "Material"/"Materials" is defined as any and all gross and microscopic tissue excised from a Plaintiff, including gross specimens, cytology and preserved tissue in paraffin blocks, ribbons, scrolls, and original and recut histology slides.

IV. INTENT

7. It is the intention of the Parties that all Material be preserved in a manner that permits the Parties equal access to and analysis of the Material.

V. PROTOCOL FOR REQUESTING AND HANDLING OF MATERIALS CURRENTLY AVAILABLE AT A FACILITY

8. To the extent that Materials exist for any Plaintiff, unless the Materials have already been obtained, such Plaintiff will obtain the Materials from the Facilities currently in possession of the Materials, and will maintain the Materials in an appropriate manner that preserves

them for examination, testing and use by both parties. Plaintiffs shall notify Defendants when Plaintiff requests the Materials and shall notify Defendants within *14 days, but no longer than 21 days if there are extenuating circumstances*, after receipt of the Materials. Such notice shall be provided by email to: (1) Johnson & Johnson Defendants: **HAHERN@shb.com** and **lbacon@shb.com**; (2) Imerys: **ImerysMDLpathology@grsm.com** and **talcpathology@coughlinlinduffy.com**; and (3) PCPC: **tlocke@seyfarth.com** and **ebarton@seyfarth.com**. The notification shall confirm the type and number of Materials obtained, the facility from which the Materials were received, the date of the procedure from which the Materials were obtained and the associated laboratory accession numbers. If the date of the procedure is unknown, Plaintiffs shall take all reasonable steps to obtain the date of the procedure and to provide Defendants with such information immediately upon receipt. The parties agree that Plaintiffs and Defendants shall document the chain of custody for all Materials using the form attached as Exhibit A.

9. Plaintiffs will request of the Facility that they preserve and maintain, for Defendants' use, at least one-half of any preserved Material that Plaintiffs obtains from a Facility and request that the Material be photographed prior to dividing the tissue as agreed to above.

a. In the event that any of the Materials contain an amount of tissue that is too small to be divided equally among the parties ("Small Sample"), the parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol as to that specific tissue sample. Neither party will perform any review, analysis, or testing on the Small Sample or alter the Small Sample in any way prior to reaching a mutually agreeable protocol. In the event no agreement can be reached, the parties will seek the Court's guidance.

b. If, in the course of dividing the Materials to preserve at least one-half for use by Defendants, it becomes impossible to provide Defendants with Materials that can be used in the same manner that Plaintiffs are able to use their half of Materials, Plaintiffs will notify Defendants. The parties agree to meet and confer and attempt to arrive at a mutually agreeable protocol as to the Materials. Neither party will perform any review, analysis, or testing on the Materials or alter the Materials in any way prior to reaching a mutually agreeable protocol. In the event that no agreement can be reached, the parties will seek the Court's guidance.

c. Paragraphs 8a and 8b shall only apply if the amount of the Materials is such that it cannot be divided in a manner that would permit analysis of a representative and equal sample of tissue by both parties, and shall not operate to restrict Plaintiffs' utilization of the Materials under any other circumstances not stated within this Order.

VI. PROTOCOL FOR HANDLING OF CURRENTLY AVAILABLE MATERIALS EXISTING IN POSSESSION OR CONTROL OF PLAINTIFFS

10. To the extent that Materials have already been requested and obtained by any Plaintiff, such Plaintiff shall within *14 days, but no longer than 21 days if there are extenuating circumstances*, provide to Defendants the type and number of Materials obtained, the facility from which the Materials were originally received, the date of the procedure from which the Materials were obtained, and the associated laboratory accession numbers. If the date of the procedure is unknown, Plaintiffs shall take all reasonable steps to obtain the date of the procedure and to provide Defendants with such information immediately upon receipt. Plaintiffs will also provide chain of custody information for such Materials that are already in possession of Plaintiffs or Plaintiffs' representative. The Parties agree that the chain of custody information will be provided to Defendants at the time of Plaintiff's expert disclosures, to avoid premature disclosure of experts.

PROTOCOL FOR HANDLING SLIDES

11. Plaintiffs agree to provide Defendants with any original and recut slides obtained from a Facility (the “Slides”) within *seven (7) days, but no longer than 14 days if there are extenuating circumstances*, after service of Plaintiffs’ expert disclosures. Plaintiffs will maintain the Slides in an appropriate manner that preserves them for examination, testing and use by both parties.

12. In the event a Plaintiff requests recut histology slides from a Facility, Plaintiff agrees to request that enough preserved tissue exists for a duplicate set of slides to be created for Defendants’ use. If there is not enough preserved tissue to provide Defendants with a duplicate set of recut slides, the parties will meet and confer and attempt to arrive at a mutually agreeable protocol as to the handling and disposition of the Materials.

13. To the extent Defendants require additional recuts from a Facility, Defendants will make such request to Plaintiffs’ counsel. Plaintiffs’ counsel shall make such request of the facility maintaining the pathology block and request duplicate stained slides for both parties with each party to bear its own costs of such recut and duplication. The parties agree that Plaintiffs will provide Defendants all slides (originals and/or re-cuts) reviewed by Plaintiffs’ experts within *seven (7) days, but no longer than 14 days if there are extenuating circumstances*, after service of Plaintiffs’ expert disclosures and that Defendants will do the same with regard to slides reviewed by Defendants’ experts.

11. Following review by Defendants’ experts and/or consultants, the Materials shall be returned to Plaintiff’s counsel or the Facility from which Defendants received the Materials.

VII. NOTICE TO THE FACILITY

12. This Order specifically authorizes and directs any Facility in possession of any Materials for a Talcum Powder MDL Plaintiff to provide the Materials to Plaintiffs' counsel when requested, assuming Healthcare Insurance Portability and Accountability Act requirements are otherwise satisfied.

13. Nothing herein shall be construed to limit or constrain the ability of healthcare providers to do what is necessary for the care and treatment of a Plaintiff.

VIII. THE ORDER

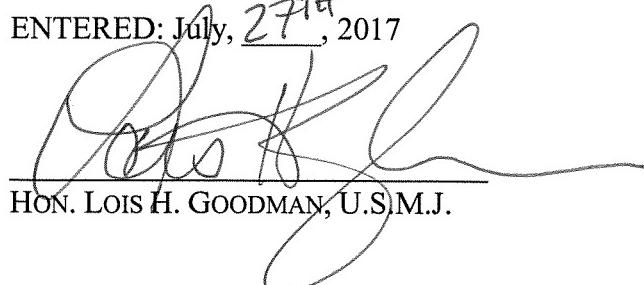
14. Neither this Order nor service of a copy of this Order upon non-parties shall affect any Party or non-party's objections to personal jurisdiction, including any rights to service of process or subpoenas under applicable law. This Order is not intended to address the discoverability or admissibility at trial of any pathology tissue. The Parties' rights to object to the discoverability or admissibility of any pathology tissue under the Federal Rules of Civil Procedure are not impaired in any way by this Order.

15. This Order does not supplant, restrict or limit any obligation existing at common, federal and/or statutory law in any jurisdiction relating to a Party's obligation to preserve objects or things in their possession, custody or control.

16. The Court hereby accepts the stipulation of the parties. The court **DIRECTS** the Clerk to file a copy of this order in 3:16-md-2738-FLW-LHG and it shall apply to all cases. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by

the court. The orders may be accessed through the CM/ECF system or the court's website at <http://www.njd.uscourts.gov/>.

ENTERED: July, 27th, 2017



HON. LOIS H. GOODMAN, U.S.M.J.

89637842.1

EXHIBIT A

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____

Law Firm: _____ Surgery Date: _____

ENTRY NO. 1: Pick Up Location / Releasing, Party Information

Facility Name: _____

Address: _____

Address: _____

Contact Name: _____ Department: _____

Contact Phone #: _____ Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____

(3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 1: Recipient Location/Receipt information:

Facility Name: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____

(3) _____ (4) _____

Note any changes of condition:Condition of specimen: ambient () , frozen () , unfrozen () , refrigerated ()Condition of Container: undamaged () , damaged () , describe: _____Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
 Law Firm: _____ Surgery Date: _____

ENTRY NO. 2: Pick Up Location / Releasing, Party Information

Facility Name: _____
 Address: _____
 Address: _____

Contact Name: _____ Department: _____

Contact Phone #: _____ Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____
 (3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 2: Recipient Location/Receipt information:

Facility Name: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____
 (3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient () , frozen () , unfrozen () , refrigerated ()

Condition of Container: undamaged () , damaged () , describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

CHAIN OF CUSTODY FORM FOR PATHOLOGY MATERIALS

Patient Name: _____ Date: _____
 Law Firm: _____ Surgery Date: _____

ENTRY NO. 3: Pick Up Location / Releasing, Party Information

Facility Name: _____
 Address: _____
 Address: _____

Contact Name: _____ Department: _____

Contact Phone #: _____ Contact Email: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____
 (3) _____ (4) _____

Person RELEASING Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____

ENTRY NO. 3: Recipient Location/Receipt information:

Facility Name: _____

Item Description (include manner of preservation, size of specimen, slide number and any other identifying mark(s)).

(1) _____ (2) _____
 (3) _____ (4) _____

Note any changes of condition:

Condition of specimen: ambient (), frozen (), unfrozen (), refrigerated ()

Condition of Container: undamaged (), damaged (), describe: _____

Person **RECEIVING** Shipment: _____ (sign/print)

Date: _____ Time: _____

Witness: _____ (sign/print)

Date: _____ Time: _____